

REMARKS

Applicants thank the Examiner for withdrawing the restriction and rejoining Groups I and II.

After entry of this amendment, claims 1-13, 15-18, and 20-24 are pending of which claims 10 and 11 are withdrawn. Claims 14 and 19 are cancelled without prejudice or disclaimer. The claims have been amended without prejudice or disclaimer and the amendments find support *inter alia* in the original claims. The amendment to claim 1 finds further support in the specification, for example, at page 3, lines 17-20, and in the Examples. The amendments to claims 4, 16, and 21 find further support in the specification, for example, at page 6, lines 8-11, at page 8, lines 2-7, and in Example 2. The amendments to claim 5 find further support in the specification, for example, at page 6, lines 8-11, at page 8, lines 2-7, 19 and 33-37, and at page 9, lines 1-31. The amendments to claim 8 find further support in the specification, for example, at page 3, lines 17-20, at page 6, lines 8-11, at page 8, lines 2-7, and in the Examples. The amendments to claim 13 find further support in the specification, for example, at page 6, lines 8-11, at page 8, lines 2-7, at page 14, line 33, and in Example 2. No new matter has been added.

Rejections under 35 U.S.C. § 112, first paragraph

Claim 5 was rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the written description requirement. Applicants respectfully traverse.

First, please note that claim 5, which depends from claim 1, is not directed to a nucleic acid but rather relates to a method for increasing plant yield relative to corresponding wild type plants, comprising introducing into a plant a nucleic acid encoding a D-type Cyclin Dependent Kinase (CDKD) resulting in a transgenic plant having increased plant yield relative to a corresponding wild type plant. As set forth in *Vas-Cath Inc. v. Mahurkar*, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991), the test for determining compliance with the written description requirement is whether the disclosure of the application as originally filed reasonably conveys to one skilled in the art that the inventor had possession of the claimed subject matter at the time of filing. According to the "Guidelines for the Examination of Patent Applications Under the 35

U.S.C. 112, ¶ 1, ‘Written Description’ Requirement,” at page A-6, 3rd column of the “Written Description Training Materials” (“Guidelines,” March 25, 2008 revision), possession of an invention can be shown “in a variety of ways, including description of an actual reduction to practice.” The present application describes an actual reduction to practice of the claimed method in Example 3. Thus, possession of the claimed method is shown, and the rejection should be withdrawn.

Possession can also be shown “by showing that the invention was ‘ready for patenting’ such as by the disclosure of structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention.” MPEP § 2163 (citations omitted). A written description of an invention involving a nucleic acid, like a description of a chemical genus, “requires a precise definition, such as by structure, formula, [or] chemical name,” of the claimed subject matter sufficient to distinguish it from other materials. *Fiers v. Revel*, 984 F.2d 1164, 1171 (Fed. Cir. 1993) (emphasis added). For a claimed genus, the written description requirement may be satisfied through sufficient description of a representative number of species by actual reduction to practice, by disclosure of relevant identifying characteristics, by functional characteristics coupled with known or disclosed correlation between function and structure, or by a combination of such identifying characteristics. *See Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997).

The Examiner appears to base the rejection on the recitation of “functional variants” alleging that neither the specification nor the prior art describe the structure of any functional variant of SEQ ID NO: 1 and 2. Applicants respectfully disagree. However in order to expedite prosecution, claim 5 has been amended without prejudice or disclaimer to recite the method with further specificity. Claim 5 as amended does not recite “functional variants” and relates to a method using a nucleic acid which encodes a CDKD comprising an NXTALRE motif and a catalytic kinase domain. Accordingly, in light of the amendments, the rejection is believed to be rendered moot.

Nonetheless, the specification discloses at least four CDKDs, as shown in the CDKD cluster depicted in Figure 1 and described in the specification at page 2, lines 36-37, at page 3,

lines 1-8, at page 6, lines 25-27. The specification also provides in one embodiment the use of a CDKD;1 from *Arabidopsis* as represented by its nucleic acid sequence SEQ ID NO: 1 and the corresponding amino acid sequence SEQ ID NO: 2. Thus, the structure of the claimed “nucleic acid” is provided. Furthermore, the specification discloses relevant identifying characteristics of the sequences sufficient to distinguish CDKD sequences from other materials. For example, as explained at pages 5-6 of the specification and depicted in Figure 1, CDKDs fall within a separate group when compared to other types of CDKs. Additionally, CDKDs are also characterized by various domains, motifs, and conserved regions. For example, CDKDs can comprise an NXTALRE motif and a catalytic kinase domain (see specification, for example, at page 6, lines 1-30). Thus the specification not only provides a representative number of species of CDKDs but structural characteristics sufficient to distinguish CDKDs from other materials.

Furthermore, functional variants of CDKDs are described in the specification, for example at pages 8-13, which include natural variations, such as alternative splice variants, allelic variants, polymorphisms, which can lead to alterations in the amino acid sequences within a population without altering the functional activity of the CDKD. Accordingly, the claim includes the use of the expected range of natural variants, which should certainly be within the scope of the invention. As stated in *Capon v. Eshhar*, the descriptive text needed to meet the written description requirement varies with the nature and scope of the invention at issue, as well as the scientific and technologic knowledge already in existence. *Capon v. Eshhar*, 418 F.3d 1349, 1357 (Fed. Cir. 2005). “When the prior art includes the nucleotide information, precedent does not set a *per se* rule that the information must be determined afresh.” *Id.* at 1358. Here, the specification describes several CDKDs, structural genes, and expression techniques such that the nucleic acids used in the method can be prepared. In addition, the specification shows by way of working examples that the claimed method results in plants having increased yield when using a nucleic acid encoding a CDKD (an actual reduction to practice). See Specification at pages 23-27, Example 3 and Tables 1-5. Under these circumstances, compliance with the written description requirement should not involve listing the nucleotide sequences of known CDKDs, since that information was readily known and available to the skilled reader. See, *Falkner v. Inglis*, 448 F.3d 1357, 1368 (Fed. Cir. 2006) (“Indeed, a requirement that patentees recite known DNA structures, if one existed, would serve no goal of the written description requirement”); *In*

re Buchner, 929 F.2d 660, 661 (Fed. Cir. 1991) (A patent need not disclose what is well known to those skilled in the art and preferably omits that which is well known to those skilled and already available to the public).

The specification therefore not only discloses a representative number of species but additionally discloses structural characteristics sufficient to distinguish CDKDs from other materials. Thus the specification provides adequate written description for the present claims under both alternatives of the *Lilly* standard. See *Eli Lilly and Co.*, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997) (holding that “[a] description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs defined by nucleotide sequence . . . or of a recitation of structural features common to members of the genus.”). See also *In re Angstadt*, 537 F.2d 498 (CCPA 1976) (holding that there has never been a requirement that every species encompassed by a claim must be disclosed or exemplified in a working example).

Reconsideration and withdrawal of the rejection is respectfully requested.

Rejections under 35 U.S.C. § 112, second paragraph

Claims 4-5 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for the recitation of “functional variant.” Claim 5 was additionally rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for the recitation of “capable of.” Claims 5 and 21 were also rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for the recitation of “amino acid” rather than “amino acid sequence.” The claims have been amended without prejudice or disclaimer. In light of the amendments, the rejections are believed to be rendered moot. Reconsideration and withdrawal of the rejection is respectfully requested.

Rejections under 35 U.S.C. § 102

Claims 13-14 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by *Fabian-Marwedel et al.* (hereinafter “Fabian-Marwedel”). Applicants respectfully traverse. However, in order to expedite prosecution, the claims have been amended without disclaimer or

prejudice. Furthermore, claim 14 is cancelled without prejudice or disclaimer. Thus the rejection as to claim 14 is rendered moot.

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegall Bros., Inc. v. Union Oil Co.*, 814 F.2d 628, 631 (Fed. Cir. 1987). “Rejections under 35 U.S.C.S. § 102 are proper only when the claimed subject matter is identically disclosed or described in the prior art. Thus, it is not enough that the prior art reference discloses part of the claimed invention, which an ordinary artisan might supplement to make the whole, or that it includes multiple, distinct teachings that the artisan might somehow combine to achieve the claimed invention. The prior art reference must clearly and unequivocally disclose the claimed invention or direct those skilled in the art to the invention without any need for picking, choosing, and combining various disclosures not directly related to each other by the teachings of the cited reference.” *Net MoneyIN Inc. v. VeriSign Inc.*, 545 F.3d 1359 (Fed. Cir. 2008) (holding “that unless a reference discloses within the four corners of the document not only all the limitations claimed but also all of the limitations arranged or combined in the same way as recited in the claim, it cannot be said to prove prior invention of the thing claimed and, thus, cannot anticipate under 35 U.S.C. § 102.”).

Fabian-Marwedel teaches use of a maize ubiquitin promoter in their construct. Fabian-Marwedel does not teach use of a control sequence capable of driving expression of the nucleic acid sequence of which comprises at least a GOS2 promoter as required by the present claims. Therefore, Fabian-Marwedel does not teach or disclose all the elements of the construct as presently claimed nor all the limitations arranged in the same way as recited in the present claims, and as such cannot anticipate the claims. Reconsideration and withdrawal of the rejection is respectfully requested.

Rejections under 35 U.S.C. § 103

Claims 1-9, 12, 15, 18, 20-21, and 23-24 were rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Fabian-Marwedel in view of Komari *et al.* (hereinafter “Komari”). Applicants respectfully disagree and traverse the rejection.

The examiner bears the initial burden of establishing *prima facie* obviousness. See *In re Rijckaert*, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993). To support a *prima facie* conclusion of obviousness, the prior art must disclose or suggest all the limitations of the claimed invention. See *In re Lowry*, 32 F.3d 1579, 1582, 32 USPQ2d 1031, 1034 (Fed. Cir. 1994).

The Examiner relies on Fabian-Marwedel for teaching rice plants cells transformed with a construct comprising a CDKD encoding nucleic acid, a maize ubiquitin promoter, and a nopaline synthase terminator sequence. The Examiner contends that Fabian-Marwedel further teaches that increasing the abundance R2 abundance accelerates S-phase progression and growth rate in suspension cells. The Examiner acknowledges that Fabian-Marwedel does not teach a transformation method where transgenic plants are produced. The Examiner relies on Komari for teaching transformation methods wherein transgenic cereal plants are produced. The Examiner also acknowledges that neither Fabian-Marwedel nor Komari teach a transgenic plant having increased yield or increasing plant yield relative to a corresponding wild type plant. However, the Examiner has not given patentable weight to this limitation, alleging that these are intended uses in the preamble and not limiting. Applicants strongly disagree with the Examiner's characterization of the references and conclusions.

First regarding the preamble, the MPEP and the Federal Circuit are clear as to when a claim preamble should be given patentable weight. “[A] claim preamble has the import that the claim as a whole suggests for it.” *Bell Communications Research, Inc. v. Vitalink Communications Corp.*, 55 F.3d 615, 620, 34 USPQ2d 1816, 1820 (Fed. Cir. 1995). “If the claim preamble, when read in the context of the entire claim, recites limitations of the claim, or, if the claim preamble is ‘necessary to give life, meaning, and vitality’ to the claim, then the claim preamble should be construed as if in the balance of the claim.” *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165-66 (Fed. Cir. 1999). *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951) (A preamble reciting “An abrasive article” was deemed essential to point out the invention defined by claims to an article comprising abrasive grains and a hardened binder and the process of making it. The court stated “it is only by that phrase that it can be known that the subject matter defined by the claims is comprised as an abrasive article. Every union of substances capable *inter alia* of use as abrasive

grains and a binder is not an ‘abrasive article.’” Therefore, the preamble served to further define the structure of the article produced.). In *Poly-America LP v. GSE Lining Tech. Inc.*, 383 F.3d 1303, 1310, 72 USPQ2d 1685, 1689 (Fed. Cir. 2004), the court stated that “a ‘[r]eview of the entirety of the ‘047 patent reveals that the preamble language relating to ‘blown-film’ does not state a purpose or an intended use of the invention, but rather discloses a fundamental characteristic of the claimed invention that is properly construed as a limitation of the claim....’” Additionally, clear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art transforms the preamble into a claim limitation because such reliance indicates use of the preamble to define, in part, the claimed invention. See also MPEP § 2111.02.

Applicants respectfully disagree that the preamble recites an intended use. For example, claim 8 relates to a method of producing a transgenic plant. A transgenic plant is not an intended use but clearly a product produced by the method. Thus a plant with increased yield relative to a corresponding wild-type plant rather discloses a fundamental characteristic of the claimed invention that should be properly construed as a limitation of the claim as in *Poly-America LP*. Nonetheless in order to expedite prosecution, the claims have been amended without disclaimer or prejudice and relate to a method which results in a transgenic plant having increased plant yield relative to a corresponding wild type plant and to a construct comprising a CDKD-encoding nucleic acid and a control sequence which comprises a GOS2 promoter. Because neither Fabian-Marwedel nor Komari teach a transgenic plant having increased yield or increasing plant yield relative to a corresponding wild type plant nor the claimed construct, Fabian-Marwedel and Komari, alone or in combination, do not disclose or suggest all the limitations of the claimed invention. Accordingly, a *prima facie* case of obviousness has not been established for this reason alone.

The Examiner further alleges that the nucleic acid taught by Fabian-Marwedel is capable of hybridizing to the sequence of SEQ ID NO: 1 based on a best local similarity of 71.3%. Applicants strongly disagree. Based on the sequence alignment provided by the Examiner, only a 39.8% identity was found over 924 bases from a total of 1764 bases of the sequence of Accession No. X58194 dated April 18, 2005. The identity based on the full-length sequence of

SEQ ID NO: 1 would thus be much less than 39.8% identity. It is the Examiner's burden to establish *prima facie* obviousness. The Examiner has not established that hybridization under the conditions set forth in the claims and the specification could occur with such a low percent identity over only a portion of the SEQ ID NO: 1.

The Examiner concludes that it would be obvious to produce plants based on the teaching of Komari from the rice plant cells of Fabian-Marwedel transformed with a construct comprising a rice plant CKD-activating kinase R2 encoding nucleic acid and a maize ubiquitin promoter. The Examiner alleges that one skilled in the art would have a reasonable expectation of success given that Fabian-Marwedel overexpressed the nucleic in rice plant cells and the success of producing transgenic plants by Komari. Applicants strongly disagree that it would be obvious to produce transgenic plants from the plant cells of Fabian-Marwedel.

A reasonable expectation of success must be established for a proposed combination of references to render claims *prima facie* obvious. See MPEP § 2143.02 (citing *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986)). In addition, the record must provide evidence that those of skill in the art would have had a reasonable expectation of success in doing so. See *In re Dow Chemical Co.*, 837 F.2d 469, 473, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988); *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991).

The teachings of Fabian-Marwedel relate to an effect observed in suspension cells. There is no indication in either Fabian-Marwedel or Komari that this effect could be reproduced in whole plants. Even if an increase in growth rate were observed, there is no indication whether this growth rate, *i.e.* increased speed of growth, would translate into an increase in plant yield. An increased growth rate in suspension cells using a ubiquitin promoter does not provide any teaching or suggestion whether an increase in growth rate would occur in a whole plant or would occur throughout the entire life cycle of a plant or whether it would be restricted to certain cells, tissues or organs or to certain developmental stages, or whether an increase in speed of growth would lead to greater yield. Thus, assuming *arguendo* that it would be obvious to produce transgenic plants from the plant cells of Fabian-Marwedel, the record does not provide any evidence that there would be an expectation of success that the method would result in transgenic plants having increased yield relative to a corresponding wild-type plant as required. "The mere

fact that a certain thing *may* result from a given set of circumstances is not sufficient.” *See In re Rijckaert*, 9 F.3d 1531, 1534 (Fed. Cir. 1993).

Moreover, a prior art reference must be considered in its entirety, *i.e.*, as a whole, including portions that would lead away from the claimed invention. *See MPEP § 2141.03 (VI)* (citing *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984)). Cornejo *et al.* (hereinafter “Cornejo”), cited by the Examiner below, characterizes the expression of the ubiquitin promoter in transgenic calli and plants. Cornejo teaches that seed set in the transgenic R₀ plants was reduced compared to untransformed plants (Cornejo, page 577, left column, second full paragraph). Thus, one of ordinary skill in the art would not have a reasonable expectation of success of obtaining plants with increased yield based on the teaching of Fabian-Marwedel of a construct comprising a rice plant CDK-activating kinase R2 encoding nucleic acid and a maize ubiquitin promoter, where Cornejo teaches that use of the same promoter resulted a decreased seed yield in transgenic plants. Thus contrary to the Examiner’s conclusion, based on the teaching of Cornejo, a reference cited by the Examiner, a plant transformed with the construct of Fabian-Marwedel comprising a ubiquitin promoter would be expected to have decreased yield. Accordingly, a *prima facie* case of obviousness has not been established for this additional reason.

Furthermore, in *In re Antonie* the court found that the prior art did not reveal the property which appellant discovered and, therefore, there was no basis to find obviousness. *In re Antonie*, 559 F.2d 618, 619-620 (CCPA 1977) (The claimed wastewater treatment device had a tank volume to contractor area of 0.12 gal./sq. ft. The court found the invention as a whole was the ratio of 0.12 and its inherent property that the claimed devices maximized treatment capacity regardless of other variables in the devices. The prior art did not recognize that treatment capacity was a function of the tank volume to contractor ratio, and therefore the parameter optimized was not recognized in the art to be a result-effective variable.); *see also In re Shetty*, 566 F.2d 81, 86 (CCPA 1977) and *In re Naylor*, 369 F.2d 765, 768 (CCPA 1966); *see also MPEP § 2141.02 V*. Obviousness cannot be predicated on what is unknown. *See In re Rijckaert*, 9 F.3d at 1534 (citing *In re Spormann*, 363 F.2d 444, 448 (CCPA 1966); *see also In re Shetty*, 566 F.2d 81, 86 (CCPA 1977) and *In re Naylor*, 369 F.2d 765, 768 (CCPA 1966). Because the

references cited by the Examiner do not teach, suggest or even mention a method which results in a transgenic plant having increased yield relative to a corresponding wild-type plant, there is no basis for finding obviousness. Moreover, analogous to *In re Antonie*, Fabian-Marwedel did not recognize from expression of the gene in a cell suspension that increased plant yield in a whole plant could result. For this additional reason, a *prima facie* case of obviousness has not been established.

Because Fabian-Marwedel and Komari do not teach all the limitations of the claims, because the record does not provide any evidence of a reasonable expectation of success, because the teaching of the Cornejo reference leads away from the claimed invention and from an expectation of success, Fabian-Marwedel and Komari, alone or in combination, do not render the claims obvious. Reconsideration and withdrawal of the obviousness rejection is respectfully requested for the independent claims and the claims dependent therefrom. See *In re Fine*, 837 F.2d 1071, 1076 (Fed. Cir. 1988) (holding that if an independent claim is nonobvious then any claim dependent therefrom is nonobvious).

Claims 16-17 and 24 were also rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Fabian-Marwedel in view of Komari and Cornejo. Applicants respectfully disagree and traverse the rejection. However, in order to expedite prosecution, the claims have been amended without prejudice or disclaimer and relate to transgenic plants having increased yield which comprise the construct of claim 13.

The explanations provided above for Fabian-Marwedel and Komari are equally applicable to this rejection and are incorporated herein in their entirety.

As explained above neither Fabian-Marwedel nor Komari teach a transgenic plant having increased yield relative to a corresponding wild type plant which comprises a CDKD encoding nucleic acid. Cornejo does not remedy the deficiency of Fabian-Marwedel and Komari. Because neither Fabian-Marwedel nor Komari nor Cornejo teach or suggest a transgenic plant having increased yield relative to a corresponding wild type plant, Fabian-Marwedel, Komari, and Cornejo, alone or in combination, do not disclose or suggest all the limitations of the claimed

invention. Accordingly, a *prima facie* case of obviousness has not been established for this reason alone.

Moreover, a prior art reference must be considered in its entirety, *i.e.*, as a whole, including portions that would lead away from the claimed invention. See MPEP § 2141.03 (VI) (citing *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984)).

Cornejo teaches the use of the maize ubiquitin promoter in transgenic calli and plants. Cornejo describes that the ubiquitin promoter is expressed in many, but not all, rice tissues and undergoes important changes in activity during development of transgenic plants, where, for example, expression decreased with age of the plant in roots and leaves (see Cornejo, abstract, and page 577). Additionally, Cornejo teaches that seed set in the transgenic R₀ plants was reduced compared to untransformed plants (Cornejo, page 577, left column, second full paragraph). Therefore, one skilled in the art would not be motivated to use a ubiquitin promoter to produce a plant having increased yield, since Cornejo teaches that the use of the ubiquitin promoter leads to the opposite result, *i.e.* reduced seed set.

Further as explained above, one of ordinary skill in the art would not have a reasonable expectation of success of obtaining plants with increased yield based on the teaching of Fabian-Marwedel of a construct comprising a rice plant CDK-activating kinase R2 encoding nucleic acid and a maize ubiquitin promoter, where Cornejo teaches that use of the same promoter resulted in decreased seed yield in transgenic plants. Accordingly, a *prima facie* case of obviousness has not been established for this additional reason.

For at least these reasons, reconsideration and withdrawal of the rejection is respectfully requested for the independent claims and the claims dependent therefrom. See *In re Fine*, 837 F.2d 1071, 1076 (Fed. Cir. 1988) (holding that if an independent claim is nonobvious then any claim dependent therefrom is nonobvious).

CONCLUSION

For at least the above reasons, Applicants respectfully request withdrawal of the rejections and allowance of the claims. If any outstanding issues remain, the Examiner is invited to telephone the undersigned at the number given below.

Accompanying this response is a petition for a two month extension of time to and including January 21, 2009, pursuant to 37 CFR § 1.7(a), to respond to the Office Action mailed August 19, 2008 with the required fee authorization. No further fee is believed due. However, if an additional fee is due, the Director is authorized to charge our Deposit Account No. 03-2775, under Order No. 14546-00001-US from which the undersigned is authorized to draw.

Respectfully submitted,

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